

**Notice of Allowability**

Application No.

10/614,534

Applicant(s)

PFLAUM, ZLATKO

Examiner

Art Unit

Robert Shiao

1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to responses filed on 08/30/2004.
2. ☒ The allowed claim(s) is/are 1-13, and 15-17, now are 1-16.
3. ☒ The drawings filed on 07 July 2003 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 10/149,348.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.  |

**DETAILED ACTION**

1. This application claims benefit of the foreign application, Slovenia P-9900271 with a filing date 12/10/1999.
2. Amendment of claim 1 and a terminal disclaimer in the amendment filed on August 30, 2004, is acknowledged. Claims 1-17 are pending in the application.

***Responses to Amendment***

3. Since the limitation of the "solvents of a second type" has not been incorporated, therefore, rejection of claims 1-17 under 35 U.S.C. 112, second paragraph is maintained.
4. Since the limitation of "solvents of a first type" has been incorporated in claim 1, therefore, rejection of claims 1-17 under 35 U.S.C. 103(a) has been overcome in the amendment filed on August 30, 2004.
5. Since a terminal disclaimer has been filed and entered, therefore, rejection of claims 1-17 under the obviousness-type double patenting has been overcome in the amendment filed on August 30, 2004.

***EXAMINER'S AMENDMENT***

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Barbara J. Carter on November 8, 2004. The application has been amended as follows:

In claim 1, line10, after "or a mixture thereof", insert  
--; and wherein the solvent of the second type comprises at least one solvent  
selected from the group consisting of ether solvents and aliphatic solvents--

Delete claim 14

***Reasons for Allowance***

7. The following is an examiner's statement of reasons for allowance:

Claims 1-13, and 15-17 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to process for the preparation of amorphous atorvastatin. The closest prior art of record is Kumar et al. US 6,528,660, discloses "Process for the production of amorphous atorvastatin calcium". The difference between prior art and instant claims is that the instant processes are different from the prior art (i.e., chlorinated solvents). Suggestion for modification of prior art to obtain instant processes for preparing amorphous atorvastatin, has not been found. Claims1-13, and 15-17 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*R.S.*

Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

November 8, 2004

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*11/08/04*